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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,101	08/07/2001	Stephen K. Farrand	UNL 2993.1	1891
321	7590	11/05/2003	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/924,101	FARRAND ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 July 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-43 is/are pending in the application.

4a) Of the above claim(s) 9-33 and 36-43 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8,34 and 35 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

### *Status of the claims*

1. The Office acknowledges the receipt of Applicant's Restriction Election, received 23 July 2003. Applicant elects Group I, directed to claims 1-8 and 34-35, drawn to a Gram negative bacterium having a nucleotide sequence encoding a levansucrase, with traverse. Applicant traverses, stating primarily that restriction is not proper because each of the Groups of claims have a common element, and that any search of the prior art and examination of Group I will necessarily co-extend with the search and examination of all the other Groups. Applicant's traversal has been considered and is unpersuasive because even though the searches for the various groups may overlap, they are not coextensive. Therefore, restriction is proper. Applicant further traverses that the prior art regarding an inducible regulatory sequence operatively linked to a nucleotide encoding a levansucrase gene is sufficiently sparse to allow examination of these claims without undue burden. Applicant's traversal has been considered and is unpersuasive this is a conclusory statement with no evidence offered as to the sparseness of the prior art. Accordingly this restriction is made FINAL.

2. Claims 1-43 are pending; claims 1-8 and 34-35 are examined in this action.

Claims 9-33 and 36-43 are withdrawn as being a nonelected invention.

### *Specification*

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 5, line 9, for example. Applicant is

required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 and 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, and all claims dependent thereon,

- “inducible regulatory sequence” is unclear; is this a promoter?
- “operably linked” is ambiguous because the function of “operably” is unclear. Does “operably” refer to inducibility? Or to promoter ability? or to “encoding”?
- “contained within the genome” is ambiguous; what is contained? is it the levansucrase? Or the nucleotide sequence? Or the inducible regulatory sequence?

In claim 7, the meaning of the term in the parentheses is unclear. Is this an abbreviation? Or a clarification?

Clarification and/or correction are required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Recorbet, et. al. , Conditional Suicide system of Escherichia coli released into soil that uses the Bacillus sacB gene, 1993, Applied and Environmental Microbiology, Vol. 59, No. 5, May 1993, pages 1361-1366.

Recorbet et. al. teaches a Gram-negative bacterium comprising an inducible regulatory sequence operatively linked to a nucleotide sequence encoding a levansucrase contained within the genome of said Gram-negative bacterium (Abstract, 2<sup>nd</sup> column, page 1361) and the nucleotide sequence encoding levansucrase being a sacB open reading frame (Abstract, 2<sup>nd</sup> column, page 1361).

Accordingly Recorbet anticipates the claimed invention.

8. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Fouet, et. al., Secretion-expression vectors for bacillus subtilis using the levansucrase gene signal sequence, Canada 1, 270,779, issued 26 June 1990.

Fouet, et. al. teach a Gram-negative bacterium comprising a recombinant nucleotide sequence comprising an inducible regulatory sequence other than SacR operatively linked to a nucleotide sequence encoding a levansucrase (page 6, lines 22-32).

Accordingly Fouet et. al. anticipates the claimed invention. Fouet does not teach Agrobacterium tumefaciens.

9. Claims 4 and 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Hamilton, US 5,733,744, issued 31 March 1998.

Hamilton teaches a Gram-negative bacterium comprising an inducible regulatory sequence operatively linked to a nucleotide sequence encoding a levansucrase contained within the genome of said Gram-negative bacterium , where the bacterium is a Agrobacterium tumefaciens, ( 4<sup>th</sup> column, lines 25-65),

Accordingly, Hamilton anticipates the claimed invention.

#### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1,3, 6-8 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Recorbet et. al. as applied to claims 1 and 3 above, and further in view of applicant's admitted prior art ( pages 5, 7, 8, 9, 10, and 11).

Recorbet et. al. teaches a Gram-negative bacterium comprising an inducible regulatory sequence operatively linked to a nucleotide sequence encoding a levansucrase contained within the genome of said Gram-negative bacterium (Abstract, 2<sup>nd</sup> column, page 1361) and the nucleotide sequence encoding levansucrase being a sacB open reading frame (Abstract, 2<sup>nd</sup> column, page 1361).

Recorbet does not teach Agrobacterium tumefaciens or a regulatory sequence other than sacR, the C. coil lactose operon of SEQ ID NO: 1, the Pi 2(noc) promoter and noc 1 operon (SEQ ID NO: 2), the Pbad promoter (SEQ ID NO: 5) and the araC cis element (SEQ ID NO: 4), the traCDG promoter (SEQ ID NO: 7) and the occ promoter (SEQ ID NO: 8), or a second copy of the sacB open reading frame.

Applicant's admitted prior art teaches that each of these sequences were known in the prior art and Applicant teaches that "any inducible promoter that is functional within Gram-negative bacterium can be used" (p. 5, lines 26-27).

Given the recognition of one of ordinary skill in the art of the value of a Gram-negative bacterium comprising an inducible regulatory sequence operatively linked to a nucleotide sequence encoding a levansucrase contained within the genome of said Gram-negative bacterium, which allows for gene transfer to plants without the use of

antibiotic resistance markers, and given the teaching that any inducible promoter functional in Gram-negative bacterium can be used, it would have been obvious to substitute other known promoters having the same effect. The desirability of providing a second copy of a coding sequence as "insurance" against mutations is known.

Thus the claimed inventions would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

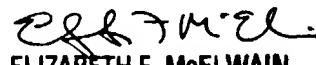
#### REMARKS

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD  
Patent Examiner  
Art Unit 1638  
November 2, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600

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